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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/474,435

12/28/1999

Yongwei Cao

16517.044/15473B

2233

66056

7590

03/18/2008

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EXAMINER

SALMON, KATHERINE D

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/474,435	Applicant(s) CAO ET AL.	
	Examiner KATHERINE SALMON	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,6-8,12-14,19-21,24-26,32-38,60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,6-8,12-14,19-21,24-26,32-38,60 and 61 is/are rejected.
- 7) ☒ Claim(s) 32-38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/13/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to papers filed in the supplemental response 1/03/2008.
2. Applicant's election of Group 1, and the election of species of transformed cell and plant cell in claims 2, 6-8, 12-14, 19-21, 24-26, 32-38, and 60-61 in the reply to restriction filed 4/20/2007 is noted. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/20/2007.
3. The following rejections for claims 2, 6-8, 12-14, 19-21, 24-26, 32-38, and 60-61 are either newly applied as necessitated by amendment or reiterated.
4. This action is FINAL.

Priority

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112.

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See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/114151 filed 12/29/1998; 60/120644 filed 2/18/1999; 60/135825 filed 5/24/1999; 60/139932 filed 6/21/1999; 60/143994 filed 7/15/1999; 09/459109 12/13/1999; 60/111990 12/14; 09/459110 12/13/1999; and 60/111991 12/14/1998, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. In the preliminary Amendment filed 4/30/2001 amended the instant specification to provide priority to the above application numbers. After a review of the prior applications, it does not appear that the instant claims have support in the above priority applications. The sequence identifiers in each case do not seem to correspond to the sequence identifiers in the instant case and therefore it does not seem that the prior filed applications have support for SEQ ID NO. 5272. For example, Application 60/114151 does not contain a SEQ ID No. 5272 and Application 60/135825 and 60/120644 both contain SEQ ID NO. 5272, but these sequences are not the same as the instantly claimed. In order to obtain priority of the prior filed applications, applicant is requested to disclose the specific sequence identifiers in each prior filed application which is identical to SEQ ID NO. 5272 of the instant application.

Response to Arguments

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The reply asserts priority to 60/139931, 60/143994, and 60/155422 encompass SEQ ID NO. 5272 (p. 9 1st two paragraphs). The reply asserts that SEQ ID No. 22273 of 60/139932 is identical to SEQ ID No. 5272 (p. 9 2nd paragraph and Attachments A-C). This argument has been fully reviewed but has not been found persuasive. SEQ ID No. 22273 does not teach the entire sequence of SEQ ID No. 5272 and therefore cannot be used to support priority to 60/139932. The reply asserts that SEQ ID No. 42735 of 60/143994 is identical to SEQ ID No. 5272 (p. 9 2nd paragraph and Attachments A-C). This argument has been fully reviewed but has not been found persuasive. SEQ ID No. 42735 does not teach the entire sequence of SEQ ID No. 5272 and therefore cannot be used to support priority to 60/143994. The reply asserts that SEQ ID No. 9911 of 60/155422 is identical to SEQ ID No. 9911 (p. 9 2nd paragraph and Attachments A-C). This argument has been fully reviewed but has been found persuasive. Therefore priority is given to application 60/155422 and therefore the priority date is 9/23/1999.

Withdrawn Objections

6. The objection to the specification made in Section 3 of the previous office action is moot based upon the amendments to the specification.

Withdrawn Rejections

7. Some of the rejection made under 35 USC 112/2nd paragraph made in Section 4 has been withdrawn based on amendments to claims or cancellation of

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claims. In so much as the rejections still apply to the amended claims the rejections are reiterated below with response to arguments following.

Rejections Necessitated by Amendment

Claim Objections

8. Claims 32-38 are objected to because they depend from a cancelled claim. The claims should be amended to depend from an amended claim or the claims should be amended to incorporate the cancelled subject matter.

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

The 35 USC 101 and 35 USC 112/First paragraph set forth below is a reiteration of the rejection set forth in the nonfinal rejection mailed 7/11/2007, response to arguments follows.

9. Claim 2, 6-8, 12-14, 1-21, 24-26, 32-38, and 60-6 rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Claims 2, 6-8, 12-14, 1-21, 24-26, 32-38, and 60-61 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a well asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2, 6-8, 12-14, 1-21, 24-26, 32-38, and 60-61 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to a substantially purified nucleic acid molecules having the sequence of SEQ ID No. 5272, substantially purified nucleic acid molecules comprising fragments of SEQ ID No. 5272 (as discussed in the 35 USC 112/second paragraph below the term “complementary” is interpreted as any fragment of SEQ ID No. 5272), and to substantially purified nucleic acid comprising a nucleic acid sequence having at least 90, 98, or 100% identity to SEQ ID NO. 5272. IN view of the “% identity” language, the claims further encompass mutants, allelic and splice variants of SEQ ID No. 5272 from non-Arabidopsis species.

The claimed nucleic acids are not supported by either a specific and substantial asserted utility or a well-established utility.

The specification discloses nucleic acid contig and singleton sequences consisting of SEQ ID Nos 1 to 81,306 were isolated from a library prepared from *Arabidopsis thaliana* ecotype Landsberg erecta tissue (p. 3 lines 17-25 and Example 1). The present claims are limited to nucleic acid comprising SEQ ID NO. 5272 or fragments of SEQ ID NO. 5272 having 90, 98, or 100% identity with SEQ ID No. 5272. The specification does not state whether nucleic acid

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molecule of SEQ ID NO. 5272 constitutes a complete open reading frame and does not identify the location of the start and stop codons.

The specification also does not set forth a particular biological activity of SEQ ID No. 5272 nor does it describe any protein encoded by SEQ ID No. 5272. Therefore the specification has not established any specific function for SEQ ID No. 5272. Further, there has been no specific use for SEQ ID NO. 5272, The specification asserts the claimed nucleic acids can be used to determine transcriptional profiling to find, identify, and characterize counterpart gene in other species (p. 2 lines 10-15). However, such uses lack a specific and substantial utility. Such uses allow only for the identification and analysis of other nucleic acids. Because a utility has not been established for the present nucleic acid, the use of this nucleic acid to search for additional nucleic acids does not constitute a "real world" context of use.

The specification further contemplates that the nucleic acid of SEQ ID NO. 5272 can be used for mapping studies, linkage analysis, constructing transgenic plants, and screening for traits or screening for polymorphisms (p. 2-3 and 17-18). However, these uses are applicable to a broad class of molecules since all plant nucleic acids could be used for these purposes. Thereby, these uses are general and do not constitute a specific utility. While the use of the nucleic acid of SEQ ID No. 5272 in the disclosed methods may eventually lead one to the identification of useful traits or specific polymorphisms or may eventually allow for the generation of transgenic plants, such uses constitute further research and

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experimentation and do not provide a readily-available, specific and substantial real-world use.

The specification also suggests that the proteins encoded by the claimed nucleic acids could be used to generate antibodies, which could be used for detection purposes (p. 16-17). Again, because a utility has not been established for the nucleic acid or the protein encoded thereby, use of the protein to generate antibodies to isolate and study proteins constitutes a research project and does not provide a specific and substantial utility.

The specification further contemplates that the nucleic acid of SEQ ID NO. 5272 can be used for identifying markers and isolate promoters associated with proteins encoded by SEQ ID No. 5272 (15-16). The utility is not specific because it is a property of all plant nucleic acids that they could be used to search for and try to identify a polymorphism or promoter. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. As stated in Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), an invention does not have utility sufficient to satisfy §101 until it is “refined and developed” to the point of providing a specific benefit in currently available form. Id at 534-35, 148 USPQ at 695. In the instant application, Applicants have not set forth a single promoter or marker, which has been identified using the claimed SEQ ID NO: 5272.

All discussions regarding polymorphisms/markers in the specification are generic in nature. There is no showing of a reasonable expectation that the claimed nucleic acids could in fact be used to identify a specific promoter or

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marker. Even if a marker could be identified using the claimed SEQ ID NO: 5272, the specification has not disclosed a specific and substantial use for such an uncharacterized marker. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. Polymorphisms are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 5272 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of plant. Therefore, the nucleic acids of SEQ ID NO: 5272 may only be used to search for polymorphisms and if such polymorphisms are identified then the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a “real-world” use in currently available form.

The specification asserts that the nucleic acids may also be used as markers and probes; to identify and obtain nucleic acid homologues, in microarray as gene-specific targets; for transformation of plants; to determine the level or expression of a protein or mRNA; to overexpress or suppress a desired protein. However, these utilities are all generic and are characteristic of all nucleic acids. Such uses do not constitute a specific utility. As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can

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only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined.

The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 5272 or a protein encoded by SEQ ID NO: 5272 or an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of an mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids. Additionally, the use of the claimed nucleic acids as a probe to detect itself does not constitute a specific utility because the result of such a use would be meaningless without additional information regarding the significance of the nucleic acid.

The use of the claimed nucleic acids to detect homologues in other plants and organisms such as alfalfa and barley (p. 21) is also not a substantial and specific utility. Since the functional activity of the presently claimed nucleic acids is unknown, and the functional activity of any putative homologues is unknown, the detection of such homologues does not provide an immediate benefit and serves only as a starting point for further research. In addition, the use of a nucleic acid in a microarray does not confer a patentable utility since all nucleic acids may be used in microarrays. Each of these asserted utilities are generic, rather than specific. Use of the claimed nucleic acids in the above manners would not be meaningful in the absence of information regarding the specific biological activity or significance of these nucleic acids.

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The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement as it applies to nucleic acids. See In re Fisher 421 F.3d 1356, 76 USPQ2d 1225 (Fed. Cir. 2005). The Court held that 35 USC 101 requires a showing that a nucleic acid is both substantial and specific, stating that “not every ‘use’ that can be asserted will be sufficient to satisfy §101.” The court emphasized that disclosing a substantial utility means “show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some further date after further research.” Simply put, to satisfy the ‘substantial’ utility requirement, an asserted use must show that claimed invention has a significant and presently available benefit to the public.” Id. 76 USPQ2d at 1230.

The Fisher Court also held that none of the uses asserted by Applicants in that case were either substantial or specific because each of the “asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world.” The Court concluded that “granting a patent to Fisher for its five claimed ESTs would amount to a hunting license because the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of Fisher’s research effort, but only tools to be used along the way in the search for a practical utility.”

The instant situation is analogous to that which was addressed in Fisher. In the present case, Applicants have not established that the claimed nucleic acid

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encodes for a protein with a specific and substantial biological activity, or that the nucleic acid or protein could be used to identify a particular trait or to detect a particular polymorphism or promoter of known function. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 6-8, 12-14, 1-21, 24-26, 32-38, and 60-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons

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set forth above, one skilled in the art would not know how to use the claimed invention.

Response to Arguments

The reply traverses the rejection. A summary of the arguments presented in the reply is set forth below with response to arguments following.

(A) The reply asserts that the claimed nucleic acid may be used “as markers and probes to identify and obtain nucleic acid homologues; in microarrays as gene-specific targets; for transformation of plants; to determine the level or expression of a protein or mRNA; to overexpress or suppress a desired protein” (p. 13 3rd paragraph). The reply asserts that these are specific utilities.

This argument has been fully reviewed but has not been found persuasive.

The specification contemplates that the nucleic acid of SEQ ID NO. 5272 can be used for mapping studies, linkage analysis, constructing transgenic plants, and screening for traits or screening for polymorphisms (p. 2-3 and 17-18). However, these uses are applicable to a broad class of molecules since all plant nucleic acids could be used for these purposes. Thereby, these uses are general and do not constitute a specific utility. While the use of the nucleic acid of SEQ ID No. 5272 in the disclosed methods may eventually lead one to the identification of useful traits or specific polymorphisms or may eventually allow for the generation of transgenic plants, such uses constitute further research and

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experimentation and do not provide a readily-available, specific and substantial real-world use.

The specification asserts that the nucleic acids may also be used as markers and probes; to identify and obtain nucleic acid homologues, in microarray as gene-specific targets; for transformation of plants; to determine the level or expression of a protein or mRNA; to overexpress or suppress a desired protein. However, these utilities are all generic and are characteristic of all nucleic acids. Such uses do not constitute a specific utility. As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined.

The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 5272 or a protein encoded by SEQ ID NO: 5272 or an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of an mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids. Additionally, the use of the claimed nucleic acids as a probe to detect itself does not constitute a specific utility because the result of such a use would be meaningless without additional information regarding the significance of the nucleic acid.

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(B) The reply asserts that a BLASTN analysis of SEQ ID No. 5272 shows a 97% identity to a nucleic acid sequence involved in metabolic pathway from carbohydrates to seed oil in *Arabidopsis thaliana* (p. 13 last paragraph). The reply shows the sequence identity of GenBank Accession Number BE524135.1 (p. 14 1st paragraph). The reply asserts high homology to an *Arabidopsis thaliana* protein is one of the embodiments of the invention and that SEQ ID No. 5272 has utility specific to and not generally applicable to any nucleic acid (p. 14 last paragraph). The reply asserts that SEQ ID No. 5272 can be used to isolate genes, map genes, and determine gene function associated with carbohydrate metabolism in *Arabidopsis thaliana* (p. 14 last paragraph).

This argument has been fully reviewed but has not been found persuasive.

The assertion of a function is based on postfiling homology to GenBank Accession Number BE524135.1. Therefore such a homology was not known at the time the instant invention was filed. Further, the homology is only 97% identical to GenBank Accession Number BE524135.1. This structural similarity is not indicative of a functional similarity. Even though there is structural similarity it is unknown if the claimed sequence (SEQ ID No. 5272) will have the same function as GenBank Accession Number BE524135.1.

(C) The reply asserts that "a 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient (*Fujikawa v. Wattanasin* p. 15 1st full paragraph). The reply asserts that the BLASTN

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analysis provides such a reasonable correlation through sequence identity (p. 15 1st full paragraph).

This argument has been fully reviewed but has not been found persuasive.

The assertion of a function is based on postfiling homology to GenBank Accession Number BE524135.1. Therefore such a homology was not known at the time the instant invention was filed. Further, the homology is only 97% identical to GenBank Accession Number BE524135.1. This structural similarity is not indicative of a functional similarity. Even though there is structural similarity it is unknown if the claimed sequence (SEQ ID No. 5272) will have the same function as GenBank Accession Number BE524135.1. Therefore the applicant has not provided a reasonable correlation through sequence identity because even one amino acid base pair difference can have functional effects.

Claim Rejections - 35 USC § 112/Written Description

The 35 USC 112/First paragraph set forth below is a reiteration of the rejection set forth in the nonfinal rejection mailed 7/11/2007, response to arguments follows.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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10. Claims 2, 6-8, 12-14, 1-21, 24-26, 32-38, and 60-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 is drawn to a substantially purified nucleic acid molecule comprising from about 30 to 300 nucleotides of SEQ ID NO. 5272 or a complement. Claim 6 defines the nucleic acid molecule as comprising one or more of a promoter region, regulatory region or intron region or parts of said regions. Claim 7 is drawn to a substantially purified first nucleic acid molecule, which is complementary to about 30 to 300 nucleotides of SEQ ID NO. 5272 or a complement. Claim 8 defines stringency conditions. Claim 12 is drawn to a substantially purified first nucleic acid homologous to SEQ ID NO. 5272 or complement wherein at least 90% of the nucleotide sequence is identical to SEQ ID NO. 5272 or complement. Claim 13 is drawn to a nucleic acid molecule 100% identical to a nonArabidopsis thaliana homologue. Claim 14 is drawn to a substantially purified nucleic acid molecule which is at least 98% identical to SEQ ID No. 5272 or complement. Claim 19 is drawn to a transformed cell comprising a homologous or complementary nucleic acid molecule comprising SEQ ID No. 5272 or complement. Claims 20-21 define a transformed cell. Claims 27-28 and 32-38 is drawn to oligonucleotide nucleic acid molecules comprising between 15 0 100 nucleotides on a support.

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The claims are drawn to substantially purified nucleic acids that are fragments of unknown size to SEQ ID No. 5272. The claims are drawn to any number of percent homology to SEQ ID No. 5272. The claims as writing are drawn to any nucleic acid which is complementary to about 30 to 300 nucleotides of SEQ ID NO. 5272 or any complement of SEQ ID NO. 5272. Under low stringency conditions a large number of nucleic acids would be complementary to SEQ ID No. 5272. These fragments would have any size and any number of percent homology to SEQ ID NO. 5272. Therefore the claims are drawn to a genus of nucleic acids of variants, homologues, and splice variants of SEQ ID No. 5272 without any defining characteristics of functional properties.

The claims define the nucleic acids in terms of their structure, but do not define the nucleic acids in terms of their functional properties. Accordingly, the claims are inclusive of nucleic acid molecules which have distinct biological activities from the nucleic acid of SEQ ID NO: 5272. The specification has not clearly set forth a biological activity for the nucleic acids of SEQ ID NO: 5272. Further, the specification does not set for a biological activity for putative mutant and allelic variants or splice variants or homologues of SEQ ID NO: 5272 which is encompassed by the broad claim language. Further, the specification does not describe the functional properties of the fragments of SEQ ID No. 5272 which is encompassed by the broad claim language.

The general knowledge in the art concerning homologues, mutants, allelic and splice variants does not provide any indication of how modification of the sequence of SEQ ID NO: 5272 will affect the functional properties of SEQ ID NO:

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5272. The structure and function of one molecule does not provide guidance as to the structure and function of other molecules. Therefore, the description of one molecule (SEQ ID NO: 5272) is not representative of a genus of homologues, splice, mutant and allelic variants of SEQ ID NO: 5272 having unspecified functional activities different from that of SEQ ID NO: 5272.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed”. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA...’requires a precise definition, such as by structure, formula, chemical name, or physical properties’, not a mere wish or plan for obtaining the claimed chemical invention”.

Accordingly, Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

The specification fails to sufficiently describe the claimed invention in clear

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and exact terms so that a skilled artisan would recognize that the applicants were in possession of the claimed invention at the time of filing.

In analysis of the claims for compliance with written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that “Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed.” (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) In the instant case, the specification fails to teach the necessary common attributes or features of the genus of encompassed nucleic acids and polymorphisms in view of the species disclosed. As such, one of skill in the art would not recognize that applicant was in possession of the genus of nucleic acids and polymorphisms encompassed by the broadly claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See page 1116).

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can

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clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

In conclusion, the limited information provided regarding SEQ ID No 5272 is not deemed sufficient to reasonably convey to one skilled in the art the description of all the fragments, mutants, homologues, and splice variants encompassed by the broad claim language.

Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

Response to Arguments

The reply traverses the rejection. A summary of the response is presented below with response to arguments.

The reply asserts that the application have disclosed a common structural feature, the nucleotide sequence of SEQ ID No. 5272 (p. 16 2nd full paragraph). The reply asserts that this distinguishes the members of the claimed genera from non-members because the skilled artisan would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences (p. 16 2nd full

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paragraph). The reply asserts that the applicant has provided a detailed chemical structure of SEQ ID NO. 5272 and therefore the nucleic acid molecules are readily identifiable (p. 17 1st paragraph). The reply asserts that the fact that the nucleic acid molecules may comprise additions sequences or variations is beside the point (p. 17 1st paragraph). The reply asserts that the examiner has offered no evidence to demonstrate why one skill in the art would reasonably doubt that the invention has not been adequately described (p. 17 last paragraph and p. 18 1st paragraph).

This argument has been fully considered but has not been found persuasive.

The genus of the claims include any fragment comprising SEQ ID No. 5272 comprising 30 to 300 nucleotide residues of SEQ ID No. 5272 and any complement which would include any sequence which shares any structure with SEQ ID No. 5272. This would include a very large genus of nucleic acids which would include every fragment of SEQ ID No. 5272, splice variants, allelic variants, and homologues of SEQ ID No. 5272. The specification does not describe the functional properties of SEQ ID No. 5272 and therefore it is unclear which modifications of SEQ ID NO. 5272 describe affect the functional properties of SEQ ID No. 5272. Therefore the skilled artisan would not know which of a very large genus of nucleic acids is functionally equivalent to SEQ ID No. 5272.

The general knowledge in the art concerning homologues, mutants, allelic and splice variants does not provide any indication of how modification of

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the sequence of SEQ ID NO: 5272 will affect the functional properties of SEQ ID NO: 5272. The structure and function of one molecule does not provide guidance as to the structure and function of other molecules. Therefore, the description of one molecule (SEQ ID NO: 5272) is not representative of a genus of homologues, splice, mutant and allelic variants of SEQ ID NO: 5272 having unspecified functional activities different from that of SEQ ID NO: 5272.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 2, 6-8, 60-61 are rejected under 35 U.S.C. 102(a) as being anticipated by GenBank Accession Number AP000604 (NCBI website October 15, 1999).

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The term “complements thereof” is not defined in the instant specification; therefore the phrase may be read broadly. The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *in re Morris* , 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *in re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111). The claims are given the broadest reasonable interpretation consistent with the indefinite claim language and specification wherein the phrase “complements thereof” can be read as any fragment which shares a percent identity with SEQ ID NO. 5272.

With regard to Claim 2, 60-61, GenBank Accession Number AP000604 discloses a sequence which would be considered a complement of SEQ ID NO. 5272. The alignment presented below shows that GenBank Accession Number AP000604 shares a complementary sequence to SEQ ID NO. 5272 at particular segments of the sequence. Further, GenBank Accession Number AP000604 comprises about 30 nucleotides complementary to SEQ ID No. 5272.

With regard to Claim 6, GenBank Accession Number AP000604 comprises the sequence of Chromosome 3, and therefore comprises nucleic acid sequence which are parts of promoter, regulatory, or intron regions.

With regard to Claims 7-8, GenBank Accession Number AP000604, discloses a substantially purified nucleic acid molecule of a complement of SEQ ID NO. 5272. Though GenBank Accession Number AP000604 does not teach hybridization conditions, the Accession Number does teach the product claimed

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therefore would encompass the same functions as the claimed nucleic acid and would therefore hybridize with sufficient stability. MPEP §2111-14, first section, states "While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." Therefore, for the purposes of examination, the functional limitations of hybridization set fourth in Claims 7-8 are considered not to have structural impact and will not be treated as limitations to the claims.

Alignment

Query represents SEQ ID NO. 5272 and Sbjct represents AP000604

Query 2068	2009	ATAGTTGGATTACGATTACTTTTGTCTTCGGAATTACTTTTGATGTATTTTCTATTCTC
Sbjct 57874	57815	ATAGTTGGATTACGATTACTTTTGTCTTAGGAATTACTTTTGATGTATTTTCTATTCTC
Query 2128	2069	TTTTGTTTTGTTTTGATGTTGATAATAACGAATTTTCCTTGAAATAAGAAAATCTGTTTC
Sbjct 57934	57875	TTTTGTTTTGTTTTGATGTTGATAATAACGAATTTTCCTTGAAATAAGAAAATCAGTTTC
Query 2188	2129	TTTTAAATTTACAATTTTATTGATAATAACATAATATTCTAAGAAATTATCTTTGTTTA
Sbjct 57994	57935	TTTCAATTTACAATTTTATTGATAATAACATAATATTCTAAGAAATTATCTTTGTTTA
Query 2248	2189	AAAAAATTGGGAAAGAAAAGATTTCAATCTCATCTCAAAGAACCTGATAATGACTATTG
Sbjct 58054	57995	AAAAAATTGGGAAAGAAAAGATTTCAATTTCTCATCTCAAAGAACCTGATAATGACTATTG
Query 2308	2249	GATTACCATTATTCCGTTTCTAAAATCTTCTTACTGTTGATTAATAAATCTCCT
Sbjct 58114	58055	GATTACCATTATTCCGTTTCTAAAATCTTCTTACTGTTGATTAATAAATCTCCT

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Query	2309	CTAAAGAAATATCTATCATCTCAATTGGTTGAGACCATTTTTAATTTACGTTGAAAAGAA
2368		
Sbjct	58115	CTAAAGAAATATCTATCATCTCAATTGGTTGAGACCATTTTTAGTTTACGTTGAAAAGAA
58174		
Query	2369	AGATCAAACAGATCAATGACACAAACTATAATTAAGGCACTAAACACTAAATGTCCTAAT
2428		
Sbjct	58175	AGATCAAACAGATCAATGACACAAACTATAATTAAGGCACTAAACACTAAATGTCCTAAT
58234		
Query	2429	TTGCATAATGCGGGACCCATGTCAATAATATTTCTCAAACGTTGTCGTTTTAGCCCATC
2488		
Sbjct	58235	TTGCATAATGCGGGACCCATGTCAATAATATTTCTCAAACGTTGTCGTTTTAGCCCATC
58294		
Query	2489	CTTCCTCCGAATCCACGCGCCACCGTCTAAGCTGCTGCGTCATTGCACGCGCCAATTTGC
2548		
Sbjct	58295	CTTCCTCCGAATCCACGCGCCACCGTCTAAGCTGCTGCGTCATTGCACGCGCCAATTTGC
58354		
Query	2549	TTTCAACCGCTCGAATCATCCCAGCTGAAACTCCAGTCACATCTTCTACTTTCTTTAAAT
2608		
Sbjct	58355	TTTCAACCGCTCGAATCATCCCAGCTGAAACTCCAGTCACATCTTCTACTTTCTTTAAAT
58414		
Query	2609	TCTGCCACGTCGTGCGTGTCTTAACGCCGAACAAAACGCCGCCGCTAAGAACACTCTCT
2668		
Sbjct	58415	TCTGCCACGTCGTGCGTGTCTTAACGCCGAACAAAACGCCGCCGCTAAGAACACTCTCT
58474		
Query	2669	TCGTCGCTCTTGGCCTCGTCTCCACAGCCAAAGCCAAAGACGCATATGAAACGACAGCGT
2728		
Sbjct	58475	TCGTCGCTCTTGGCCTCGTCTCCACAGCCAAAGCCAAAGACGCATATGAAACGACAGCGT
58534		
Query	2729	TTGTTAAATCCCTGTTTAGTCCTAACTTACCACACCAATTTACAAAAATGCCATCCGCCA
2788		
Sbjct	58535	TTGTTAAATCCCTGTTTAGTCCTAACTTACCACACCAATTTACAAAAATGCCATCCGCCA
58594		
Query	2789	CCGTAACCGCAACGGCCTTGGCATTCACTCTGTTTTCCCTCCCTCGCGCTCTGTTTACGT
2848		
Sbjct	58595	CCGTAACCGCAACGGCCTTGGCATTCACTCTGTTTTCCCTCCCTCGCGCTCTGTTTACGT
58654		
Query	2849	CACGCGTCGTTGACGATAGCTCGGAGCTTGAGACACAGTCAAGAGACGAGCAGCAAGAAG
2908		
Sbjct	58655	CACGCGTCGTTGACGATAGCTCGGAGCTTGAGACACAGTCAAGAGACGAGCAGCAAGAAG
58714		
Query	2909	AAGACGACGATTCTGAACAACATGTTGTTCTGTTGAGGCCAAGGAAGAAGAGGACCAGAAA
2968		
Sbjct	58715	AAGACGACGATTCTGAACAACATGTTGTTCTGTTGAGGCCAAGGAAGAAGAGGACCAGAAA
58774		
Query	2969	CGAAATTTTGAGTAAGAGATTTGCAATTTGGGCAAATGACACGCCGAAATGACGAGCGA
3028		

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Sbjct 58775 CGAAATTTTGAGTAAGAGATTTGCAATTTGGGCAGATGACACGCCGGAATGACGAGCGA
58834

Query 3029 AGAGAAAATTTGAGGCATGGAACCTAGCGTCACAAGAACGGCAGAGGAAGGCAGAGTCCG
3088
|||||
Sbjct 58835 AGAGAAAATTTGAGGCATGGAACCTAGCGTCACAAGAACGGCAGAGGAAGGCAGAGTCCG
58894

Query 3089 CGGCACAATGGAGATCAGCTTCGGCACCACAAAGCTCGCAAAGCTCACCATTGAGTCGA
3148
|||||
Sbjct 58895 CGGCACAATGGAGATCAGCTTCGGCACCACAAAGCTCGCAAAGCTCACCATTGAGTCGA
58954

Query 3149 TCTCTCTGGATCACCAGAAAGAAGTGAGAGAGAATTGGTTTGAATGATGATGGTGGGAA
3208
|||||
Sbjct 58955 TCTCTCT-GATCACCAGAAAGAAGTGAGAGAGAATTGGTTTGAATGATGATGGTGGGAA
59013

Query 3209 GAGAGATTTAAGGAAGAGATGTAAATGATTGAGGGAGAGAAAGAGCGGTGGAGTTTTTAT
3268
|||||
Sbjct 59014 GAGAGATTTAAGGAAGAGATGTAAATGATTGAGGGAGAGAAAGAGCGGTGGAGTTTTTAT
59073

Query 3269 GGTTCATGGTTGATGAGAGTAGTCTCTTCCACAGTTCACACATCAAAGAACTTACATGA
3328
|||||
Sbjct 59074 GGTTCATGGTTGATGAGAGTAGTCTCTTCCACAGTTCACACATCAAAGAACTTACATGA
59133

Query 3329 GCCATAATTTTTAGGGAAATGAAATGAATGGTGTGTTGTAGAATTGGAGAGAATGACGTG
3388
|||||
Sbjct 59134 GCCATAATTTTTAGGGAAATGAAATGAATGGTGTGTTGTAGAATTGGAGAGAATGACGTG
59193

Query 3389 TCGTGAGGTTTTGAGGCTGGTGAGATTATGTGGTCATTTTTAAACTATTACACTAGCCG
3448
|||||
Sbjct 59194 TCGTGAGGTTTTGAGGCTGGTGAGATTATGTGGTCATTTTTAAACTATTACACTAGCCG
59253

Query 3449 CCAAGTCATTCTGCTTCTTTTGGTGTGACGTGGAGATTTAGTCAACACTAATGTCTTTT
3508
|||||
Sbjct 59254 CCAAGTCATTCTGCTTCTTTTGGTGTGACGTGGAGATTTAGTCAACACTAATGTCTTTT
59313

Query 3509 CAGAGACTTGGTCTCATTGCAAATTGCTTCTTCTTTCTTGGTTGCTTCCATTACAT
3568
|||||
Sbjct 59314 CAGAGACTTGGTCTCATTGCAAATTGCTTCTTCTTTCTTGGTTGCTTCCATTACAT
59373

Query 3569 TTCTTCTGCATTGTTGCAGTCTTTTATATAAACTTTTATACATTGATCTTTTGTGGAATA
3628
|||||
Sbjct 59374 TTCTTCTGCATTGTTGCAGTCTTTTATATAAACTTTTATACATTGATCTTTTGTGGAATA
59433

Query 3629 CAAAACAGAAGATAATACTCTTAATTTATAATCTAAGGAGTAAGGATACAAAACACAAGG
3688
|||||
Sbjct 59434 CAAAACAGAAGATAATACTCTTAATTTATAATCTAAGGAGTAAGGATACAAAACACAAGG
59493

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Query	3689	TGTAAACTGTGGTGAACCTGTTTGGGTTCTGATCCGAAGTAGTACAACAATAGTCTATAT
3748		
Sbjct	59494	TGTAAACTGTGGTGAACCTGTTTGGGTTCTGATCCCAACTAGTACAACAATAGTCTATAT
59553		
Query	3749	CTTGAAATCTTTCACAAAATGGTTTCTTAAATAAAATGGTCTTTGAATAGCCAATCTAAA
3808		
Sbjct	59554	CTTGAAATCTTTCACAAAATGGTTTCTTAAATAAAAGGGTCTTTGAATAGCCAAGCTAAA
59613		
Query	3809	TCCAATAGCTCTGTTAAGATATATCCATAGAGCCCCTCCTACGAATCACACTGAGACCTC
3868		
Sbjct	59614	TCCAATTGCTCTGTTAAGATATATCCATAGAGCCCCTCCTACGAATCACACTGTGACCTC
59673		
Query	3869	TCCAGAGAGTTTACTTCTTTGGTATCCGACCATAATGCCTCTGGCGTATTCTAAATGCC
3928		
Sbjct	59674	TCCAGGGAGTTTACTTCTTTGTTATCCGACCATAATGCCTCTGGCGTATTCTAAATGCC
59733		
Query	3929	GGNTTTCGTAGCA 3941
Sbjct	59734	GGTTTTCGTAGCA 59746

Response to Arguments

The reply traverses the rejection. A summary of the response is presented below with response to arguments.

The reply asserts that the examiner has applied an untenable interpretation of the claims to sequences that are complementary to SEQ ID No. 5272 merely at a particular segment of SEQ ID NO. 5272 (p. 18 last paragraph). The reply asserts that GenBank Accession Number AP000604 does not disclose SEQ ID No. 5272 or the complement thereof (p. 18 last paragraph). The reply asserts that one of ordinary skill in the art would not reasonably interpret a sequence complementary to SEQ ID NO. 5272 at merely a particular segment or SEQ ID NO. 5272 as identical to SEQ ID No. 5272 or its complement (p. 19 1st paragraph).

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These arguments have been fully reviewed but have not been found persuasive.

The claims are drawn to a nucleic acid molecule comprising "from about 30 to 300 nucleic residues of the nucleic acid sequence of SEQ ID No. 5272 or complements thereof". Therefore broadly interpreted these claims are drawn to nucleic acid molecules which are complements of any part of SEQ ID No. 5272 and not merely the whole nucleic acid sequence of SEQ ID No. 5272. It has been noted in the office action (mailed 7/11/2007) that in order to limit the term "complement" to only sequences which are 100% complementary to the entire region of a claimed fragment the phrase "the complement" should be used to indicate that the complement is the entire complement of SEQ ID No. 5272. Here in this instant case" the use of "complements thereof" indicates that many fragments can be complementary to parts of SEQ ID No. 5272. Further it is noted that the claims have been amended to "about 30 to 300 nucleotide residues of the nucleic acid sequence of SEQ ID No. 5272". Therefore GenBank Accession Number AP000604 shares at least a 30 mer region with SEQ ID No. 5272 (see alignment above).

12. Claims 2, 6-8, 12-14, and 60-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5474796 December 12, 1995).

The term "complement" is not defined in the instant specification; therefore the phrase may be read broadly. The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *in*

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re Morris , 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997);
In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969);
and *in re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)
(see MPEP 2111). The claims are given the broadest reasonable interpretation
consistent with the indefinite claim language and specification wherein the
phrase “complement” can be read as any fragment which shares a percent
identity with SEQ ID NO. 5272.

With regard to Claim 2, Brennan teaches the total array represents every
possible permutation of the 10-mer oligonucleotide (Column 9, lines 53-55),
therefore Brennan teaches a 10-mer which would be a complement to SEQ ID
No. 5272.

With regard to Claim 6, Brennan teaches every possible 10-mer
oligonucleotide therefore the nucleotides would comprise a part of a promoter,
regulatory, or intron region because the claim language encompasses even up to
one nucleotide of a promoter, regulatory or intron region.

With regard to Claims 7-8, Brennan teaches a 10-mer which would be a
complement to SEQ ID No. 5272. Though Brennan does not teach hybridization
conditions, Brennan does teach the product claimed therefore would encompass
the same functions as the claimed nucleic acid and would therefore hybridize
with sufficient stability. MPEP §2111-14, first section, states “While features of
an apparatus may be recited either structurally or functionally, claims directed to
an apparatus must be distinguished from the prior art in terms of structure rather
than function.” Therefore, for the purposes of examination, the functional

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limitations of hybridization set forth in Claims 7-8 are considered not to have structural impact and will not be treated as limitations to the claims.

With regard to Claims 12 and 14, Brennan teaches a substantially purified first nucleic acid molecule (e.g. a 10 mer) which is homologous to SEQ ID No. 5272. The 10 mer would comprise 10 nucleotides that are identical to 10 nucleotides of SEQ ID No. 5272 and therefore would be at least 90% identical.

With regard to Claim 13, the 10 mer that Brennan teaches would also hybridize to any other sequence, which has the same 10 nucleotide sequence (e.g. 100% identical to non-Arabidopsis thaliana homologue).

Response to Arguments

The reply traverses the rejection. A summary of the response is presented below with response to arguments.

The reply asserts that the examiner has applied an untenable interpretation of the claims to sequences that are complementary to SEQ ID No. 5272 merely at a particular segment of SEQ ID NO. 5272 (p. 19 last paragraph). The reply asserts that the sequence encompass only encompass SEQ ID no. 5272 or its complement both of which are 3941 bases in length (p. 19 last paragraph).

The reply seems to asserting that "a complement" requires every single base pair of SEQ ID No. 5272, however, broadly interpreted this is not the case. The 10 mer of Brennan would complement a 10 mer fragment of SEQ ID No. 5272 (e.g. a probe which is complementary to a sequence) and therefore would

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be encompassed by the broad claim language. It has been noted in the office action (mailed 7/11/2007) that in order to limit the term "complement" to only sequences which are 100% complementary to the entire region of a claimed fragment the phrase "the complement" should be used to indicate that the complement is the entire complement of SEQ ID No. 5272.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number

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is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine Salmon/
Examiner, Art Unit 1634

/Ram R. Shukla/

Supervisory Patent Examiner, Art Unit 1634